

REMARKS

Claims 1-24 are listed as pending in the application, which claims have been finally rejected.

Introduction of the above amendments to the claims and reconsideration and withdrawal of the final rejection of claims 1-24 are respectfully requested.

DISCUSSION

Change in Correspondence Address

Applicants respectfully direct the Examiner's attention to the executed, concurrently submitted Change of Correspondence Address Form and request acknowledgement of the receipt of same. The undersigned Attorney was previously designated an Attorney of Record pursuant to the Declaration and Power of Attorney for Patent Application transmitted May 24, 2004, in the instant application. A copy of the aforementioned Declaration and Power of Attorney for Patent Application is transmitted concurrently herewith for the Examiner's inspection.

Rejection of Claims 1-24 under 35 U.S.C. §112, First Paragraph

In the Office Action mailed April 5, 2006, the Examiner finally rejected claims 1-24 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement for the methods of treatment of the disease states claimed therein, with the exception of fibromyalgia which was indicated as remaining allowable.

In a telephonic interview of June 7, 2006, conducted between the Examiner and Applicant's undersigned representative, it was mutually agreed that the pending claims would be amended to cancel therefrom all methods of treating

conditions other than hot flashes and fibromyalgia. It is noted for the record that Applicant's cancellation from the instantly claimed methods of the indications OCD, phobias, PTSD, restless legs syndrome, premenstrual dysphoric disorder, various concomitant disorders, and increasing slow wave sleep was made in an effort to expedite allowance of the application and should not be interpreted as a relinquishment of the formerly-claimed subject matter. Applicants reserve the right to file divisional applications directed to such matter.

In the aforementioned interview, it was further agreed that a submission would be made for the Examiner's consideration in the form of a supplemental Information Disclosure Statement demonstrating enablement of the claimed methods of treating hot flashes.

"In satisfying the enabling requirement, an application need not teach, and preferably omits, that which is well-known in the art." *Staehelin v. Secher*, 24 U.S.P.Q. 1513 (Bd. Pat. App. & Int. 1992), citing *Hybritech v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986). (emphasis added)

The instant application is reasonably enabled for the claimed methods of treating hot flashes because clinical paradigms for evaluating such regimens are within the possession of one of ordinary skill in the art. In support thereof, Applicants submit, for the Examiner's consideration, a supplemental Information Disclosure Statement citing the Nelson, et al., reference (JAMA, 295 (17), 2057-2071 (2006)), a summary review of over 30 years worth of published clinical trials directed to the evaluation of multiple classes of compounds for utility in treating hot flashes. The Examiner is encouraged to contact Applicant's undersigned representative

if copies of any of the individual references cited in Nelson, et al., are desired for inspection, or if such contact will otherwise facilitate prosecution. In view of the disclosure of Nelson, et al., and the references cited therein, Applicants submit that the ability to evaluating the compounds of the present invention for utility in treating hot flashes is well within the possession of one of ordinary skill in the relevant art. Accordingly, the application is reasonably enabled for use of the compounds disclosed therein in methods of treating hot flashes.

Reconsideration and withdrawal of the rejection of claims 1-24 are respectfully requested.

All claims currently pending are in condition for allowance. Such prompt and favorable action is respectfully solicited.

Respectfully submitted,

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